

Amendment under 37 CFR 1.111
Application No. 10/084,491
March 17, 2003

012 protective sheath is movable from the tubular portion of the fixed sheath to a position where the tip of the hollow needle is entirely covered. --

REMARKS

By this amendment, claim 1 has been cancelled and claims 2-5 and 7 have been amended. Currently, claims 2-11 are pending in the application, with claims 4, 10 and 11 being withdrawn from consideration as being directed to a non-elected invention. Applicant submits that claim 7 is a sub-generic claim which if allowed would require examination of currently withdrawn non-elected claim 4.

Applicant respectfully requests that the Examiner consider the references cited in the Information Disclosure Statement filed with the application on February 28, 2002. It is also requested that the Examiner initial and return a copy of PTO Form 1449 indicating such consideration.

Claims 1-3 and 5-9 were rejected under 35 USC 102(b) as being anticipated by Wilner (U.S. Patent No. 6,001,083). The Examiner believed that Wilner teaches a needle 101, a lower sheath section 109b, a connector 105a and a locking mechanism with a locking slot (Figs 7a-7b) and a locking projection. The

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Examiner also stated that the connector is slidably fitted inside the lower sheath section (Figs. 5-6). The Examiner also characterized Wilner as further comprising a pair of wings 301 and 302 with one wing coupled to the connector and the other wing coupled to the lower sheath section.

This rejection is respectfully traversed in view of the amendments to the claims and the remarks below.

The present invention relates to a safety indwelling syringe which allows safe disposal of a hollow needle after use and more particularly to a safety indwelling syringe which allows safe disposal of a hollow needle by pulling out a portion of its sheath in an easy operation.

A safety indwelling syringe according to the first embodiment of this invention has a hollow needle 1, a hub 2 fixed at a proximal end of the hollow needle 1, a fixed sheath 3 fitted to the hub 2, covering a portion of a proximal end of the hollow needle 1, a protective sheath 4 slidably fitted into the fixed sheath 3 and a pair of wings 5 protruding in opposite directions from the sheaths 3 and 4.

The fixed sheath 3 is a tube and it is formed with a slit 3a in the vicinity of its distal end as shown in Fig. 2. The slit 3a communicates with a front end opening 3b of the fixed sheath 3

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for slidably accommodating a proximal portion of a second wing 5b coupled to the protective sheath 4.

A locking means 7 is provided at a front end of the fixed sheath 3 and a proximal end of the protective sheath 4 for preventing the protective sheath 4 from slipping out. The locking means 7 consists of a locking slot 7a and a guide surface 7c of a tapered surface provided in the fixed sheath 3 and a locking projection 7b protruding from an outer periphery of the protective sheath 4 to be fitted into the locking slot 7a.

The protective sheath 4 is similar to the fixed sheath 3, a tube with opposite opening ends and is designed to cover the hollow needle 1 when pulled out forwardly from the fixed sheath 3 and locked.

The safety indwelling syringe of this invention is supplied with the hollow needle 1 covered by the protective sheath 4 as shown in Fig. 4. In use, the hollow needle 1 is exposed as shown in Fig. 5 to be inserted into the body of a patient with the wings 5 held by an operator. After use, the second wing 5b is held to slide by an operator to slide the protective sheath 4 forwardly or toward the tip of the hollow needle 1, housing the hollow needle 1 in the protective sheath 4, thereby enabling safe disposal without touching the body of the hollow needle 1.

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Claim 7 has been amended to recite "a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion partially covering the needle; and a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath; wherein, the protective sheath and the tubular portion of the fixed sheath have a locking means for restricting sliding movement of the protective sheath relative to the tubular portion, and the protective sheath is movable from the tubular portion of the fixed sheath to a position where the tip of the hollow needle is entirely covered".

Wilner relates to a sharps protection system and in particular to a sharps protection system for blood collection sets including those with butterfly IV intended to penetrate a person's skin. Wilner discloses that the sharps protection system of Figs. 5 and 6 includes a needle 101 with tip 111 sheath 109 and connector 105. The blood from hollow needle 101 flows out through tubing 110. A sharp protection system 300 includes butterfly members 301, 302 and a tether 305. The health care professional would press upward on wing 302 and connector 105 slides upward along wing 301 until wing 302 reaches the position shown in Fig. 6 in which tether 305 is substantially fully extended and tip 111 of needle 101 slides within sheath 109. Figs. 7a and 7b show a locking flap portion 306 which includes a

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hooked cap 310 and sidewall 311. The tip 111 of needle 101 slides between the opening between cap 310 and sidewall 311. The needle 101 is trapped within the cap 310 so as to prevent the needle 111 from sticking out of the top of sheath 109.

Wilner also discloses that in Fig. 10, two portions 501, 502 separate with section 501 remaining fixed in place. Section 502, which includes a cylindrical groove that extends from the top through the edge 508 includes a flapper assembly similar to that shown in Figs. 7a and 7b or similar structure which prevents needle tip 111 from extending outwardly once the needle tip 111 slides within wing 502. The flap assembly or other similar structure that allows only a one-way movement of needle tip 111 into wing 502, prevents wing 502 from sliding downwardly in a direction opposite to that of arrow B shown in Fig. 11.

Wilner does not disclose a fixed sheath fixing the hollow needle and having a tubular portion or the tubular portion partially covering the needle or a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath.

Wilner also does not disclose that the protective sheath and the tubular portion of the fixed sheath have a locking means for restricting sliding movement of the protective sheath relative to the tubular portion. Additionally, Wilner does not disclose a protective sheath that is movable from the tubular portion of the

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fixed sheath to a position where the tip of the hollow needle is entirely covered.

Applicant believes that the protective sheath smoothly slides through the tubular portion without any guiding members other than the tubular portion. This allows the indwelling syringe to be simply structured and allows an easy operation thereof.

Also, the protective sheath is prevented from falling off by the locking means so that the indwelling syringe can be safely disposed of. Applicant submits that Wilner discloses a locking member in Figs. 7a and 7b that does not restrict the movement of the front section so as to prevent the front section from falling off. Wilner discloses a tether in Figs. 5, 6, 10 and 11 for preventing the front section from falling off but the tether is easily fumbled by the fingers of an operator and may cause an accident.

Therefore, applicant respectfully submits that independent claim 7 clearly defines over Wilner and this rejection should be withdrawn.

Regarding dependent claims 2-6 and 8-9, applicant submits that these claims are also allowable in view of their amendments and the amendments that have been made to independent claim 1.

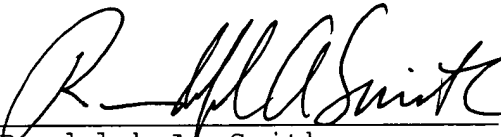
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In view of foregoing amendments and remarks, it is respectfully submitted that the pending claims 2-9 are allowable over the prior art of record, individually or in combination thereof. Thus, applicants respectfully submit that the application is now in condition for allowance and an action to this effect is respectfully requested.

If there are any questions or concerns regarding this amendment or the remarks, the Examiner is requested to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

Date: March 17, 2003


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Submitted herewith is a marked-up version of the amended claims to show changes made in the foregoing Amendment.

IN THE CLAIMS

Please substitute claims 2-5 and 7 for the pending claims with the same numbers, respectively:

-- 2. (Amended) A safety indwelling syringe as set forth in claim [1] 7, wherein the protective sheath is slidably fitted inside the tubular portion of the fixed sheath.

3. (Amended) A safety indwelling syringe as set forth in claim [1] 7, wherein the protective sheath is slidably fitted outside the tubular portion of the fixed sheath.

4. (Amended) A safety indwelling syringe as set forth in claim [1] 7, wherein the protective sheath comprises two or more slide sheaths.

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5. (Amended) A safety indwelling syringe as set forth in claim [1] 7, further comprising:

a pair of wings; wherein,

at least one of the two wings is coupled to the protective sheath so as to be [pulled for pulling out] movable with the protective sheath.--

-- 7. (Amended) A safety indwelling syringe, comprising:

a hollow needle to be inserted into a body of a patient;

a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion partially covering the needle [partly]; and

a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath; wherein,

the protective sheath and the tubular portion of the fixed sheath have a locking means for restricting [the] sliding movement of the [sheaths from one another] protective sheath relative to the tubular portion, and the protective sheath is [pulled out] movable from the tubular portion of the fixed sheath [toward] to a position where the tip of the hollow needle [and locked, covering the needle] is entirely covered. --